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**PLEASE STAMP TO ACKNOWLEDGE RECEIPT OF THE FOLLOWING:**

In re Application of: Manfred BOHN et al.

Application No.: 09/077,194

Group Art Unit: 1614

Filed: May 26, 1998

Examiner: V. Kim

For: USE OF 1-HYDROXY-2-PYRIDONES FOR THE TREATMENT OF SEBORRHEIC  
DERMATITIS

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1. Request for Rehearing Under 37 C.F.R. § 41.52 (11 pages) (in triplicate)

Dated: November 4, 2004

Docket No.: 03804.1596-00

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PATENT  
Customer No. 22,852  
Attorney Docket No. 3804.1596

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE  
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES**

In re Application of: )  
Manfred BOHN et al. ) Group Art Unit: 1614  
Application No.: 09/077,194 ) Examiner: V. Kim  
Filed: May 26, 1998 )  
For: USE OF 1-HYDROXY-2- )  
PYRIDONES FOR THE )  
TREATMENT OF SEBORRHEIC )  
DERMATITIS )

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

**REQUEST FOR REHEARING UNDER 37 C.F.R. § 41.52**

In response to the Decision on Appeal (Paper No. 36) mailed on September 15, 2004, Appellants respectfully request the Board to grant this request for rehearing in light of overlooked claim language and the timely remarks set forth below.

**REMARKS**

In the Decision, the Board vacated all pending rejections, and applied new anticipation and obviousness rejections against the appealed claims. Decision at 2-3. Specifically, the Board rejected claim 39 as anticipated by *Saint-Leger* (U.S. Pat. No. 5,650,145) (Decision at 7), claims 38-42 and 48 as anticipated by, or in the alternative as obvious over, *Saint-Leger* (Decision at 9), and claims 38-42, 48, and 53-66 as obvious in view of the combined teachings of *Saint-Leger* and *Lange* (U.S. Pat. No. 5,132,107) (Decision at 12). Below, Appellants address those new rejections in reverse order, starting with the rejection of all appealed claims appearing on pages 12-14 of the Decision.

I. **Claims 38-42, 48, and 53-66 Are Not Obvious in View of Saint-Leger and Lange**

Appealed claims 38-42, 48, and 53-66 have been rejected under 35 U.S.C. § 103 as allegedly being obvious in view of the combined teachings of *Saint-Leger* and *Lange*. Decision at 12. In support of this rejection, the Board contends that *Saint-Leger* and *Lange* are drawn to a method of treating a human patient having a symptom of seborrheic dermatitis. Decision at 8 and 13, respectively. Appellants respectfully disagree with this new ground of rejection.

The Board has interpreted Appellants' claims to read on treatments of mere symptoms of seborrheic dermatitis, rather than treatment of the underlying condition. "We interpret the phrase 'treating a human or animal patient in need of treatment for seborrheic dermatitis' [present in each appealed independent claim] as treating a

patient afflicted with any form of seborrheic dermatitis for any one or more of the symptoms associated with that disorder.” Decision at 5. In its analysis, the Board extrapolates the treatment of a symptom to meet that construction, even though the alleged prior art applied by the Board does not profess to treat any patient afflicted with seborrheic dermatitis. Appellants respectfully request the Board to reconsider this construction and its application set forth in the Decision in light of relevant case law.

A similar issue of claim construction arose in *Jansen v. Rexall Sundown Inc.*, 342 F.3d 1329, 68 U.S.P.Q.2d (BNA) 1154 (Fed. Cir. 2003). Interpreting a patent claim reciting a method of treating or preventing, the Federal Circuit framed the issue as follows: “The parties do not dispute what ‘macrocytic-megaloblastic anemia’ means; instead, they dispute how the ‘treating or preventing’ phrase and the ‘to a human in need thereof’ phrase should be read.” *Jansen*, 342 F.3d at 1332-33, 68 U.S.P.Q.2d at 1157.

Importantly, “[t]he issue reduces to whether such a human must know that he is in need of either treatment or prevention of that condition.” *Id.* That knowledge is necessary to infringe the claim, according to the Federal Circuit, because the word “need” requires the treatment or prevention of a disease, and not just a symptom. “[T]he claims’ recitation of a patient or a human ‘in need’ gives life and meaning to the preambles’ statement of purpose. *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1158 (*citing Kropa v. Robie*, 187 F.2d 150, 152, 88 U.S.P.Q. (BNA) 478, 481 (C.C.P.A. 1951)).

To enforce the idea that treating symptoms does not equate to treating diseases, the *Jansen* panel pointed to a similar case, *Rapoport v. Dement*, 254 F.3d 1053, 59 U.S.P.Q.2d (BNA) 1215 (Fed. Cir. 2001):

On appeal [in *Rapoport*] we gave weight to the ordinary meaning of the preamble phrase “for treatment of sleep apneas,” interpreting it to refer to sleep apnea, *per se*, not just “symptoms associated with sleep apnea.” *Rapoport* argued that the count was unpatentable on the ground that a prior art reference disclosed that a form of the compound recited in the claim could be administered, not for treatment of sleep apnea itself, but for treatment of anxiety and breathing difficulty, a symptom of apnea. We rejected that argument, stating, “There is no disclosure in the [prior art reference that the compound] is administered to patients suffering from sleep apnea *with the intent to cure the underlying condition.*” Thus, the claim was interpreted to require that the method be practiced with the intent to achieve the objective stated in the preamble.

*Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58 (*quoting Rapoport*, 254 F.3d at 1059 and 1061, 59 U.S.P.Q.2d at 1219 and 1221, *and adding emphasis*). As in *Jansen* and *Rapoport*, Appellants’ claims recite “in need of treatment for seborrheic dermatitis.” Accordingly, the appealed claims should be construed to require an intent to treat a human or animal patient who is suffering from the disease of seborrheic dermatitis, and not just a symptom associated with the disease.

Under such a construction, Appellants maintain that their claimed invention is not anticipated nor obvious in view of the cited documents, because “[t]here is no disclosure in the” documents cited by the Board in its Decision that compositions described in the appealed claims are “administered to patients suffering from [seborrheic dermatitis] *with the intent to cure the underlying condition.*” *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58. In *Rapoport*, the claims reciting methods of treating sleep apneas could not be invalidated by prior art that taught treatment of

*symptoms* of sleep apnea. See *Rapoport*, 254 F.3d at 1060-63, 59 U.S.P.Q.2d at 1221-22; see also *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58.

In contrast, the Decision states that “a prior art method that describes treating a patient for *at least one symptom* associated with seborrheic dermatitis is construed to anticipate or render obvious a method for treating a patient in need of treatment for seborrheic dermatitis.” Decision at 5-6 (emphasis added). Appellants respectfully contend that such a conclusion improperly infuses hindsight into the patentability analysis, and conflicts with the law set forth in *Jansen* and *Rapoport*. Therefore, Appellants request that the Board reconsider the claim construction found in the Decision, and withdraw the new rejections over the combined teachings of *Saint-Leger* and *Lange*.

**II. Claims 38, 40-42 and 48 Are Neither Anticipated by Nor Obvious in View of Saint-Leger**

Claims 38-42 and 48 have been rejected under 35 U.S.C. § 102 as anticipated by, or in the alternative, under 35 U.S.C. § 103 as unpatentable over *Saint-Leger*. Decision at 9. Appellants respectfully disagree with this rejection.

In addition to the arguments above as to why the teachings of the cited documents do not render their claims obvious, Appellants point out that the Decision is silent regarding the construction of the claim language “consisting essentially of” appearing in appealed claims 38 and 65. See Decision at 3-4. A proper claim construction that acknowledges the “consisting essentially of” language would prevent the application of *Saint-Leger* in the manner set forth in the Decision. Accordingly, Appellants respectfully submit that the Board has overlooked that claim language in its

Decision. Significantly, the new grounds of rejection should be withdrawn as to appealed claims 38, 40-42, 48 and 65, because those claims do not read upon what *Saint-Leger* describes, teaches, and suggests to one of ordinary skill in the art.

*Saint-Leger* recites “dermatological/cosmetic compositions” for reduction of hair loss containing “(a) at least one antifungal agent and (b) at least one halogenated antibacterial agent.” *Saint-Leger*, at Abstract. The examples and claims consistently disclose compositions containing those two active ingredients, and the document contains no teaching or suggestion to omit one or the other of those active ingredients in the satisfactory practice of the disclosed technology. See *Saint-Leger*, cols. 1 and 3-8.

Appealed claims 38 and 65 recite methods for treating seborrheic dermatitis by employing a composition comprising “an active component consisting essentially of at least one 1-hydroxy-2-pyridone of formula (I).” Dependent claims 40-42 and 48 incorporate that element by reference. See 35 U.S.C. § 112, ¶ 4 (2000). Accordingly, claims 38, 40-42, 48, and 65 exclude methods of treating seborrheic dermatitis employing compositions having an active component that contains additional ingredients such as *Saint-Leger*’s halogenated antibacterial agent.

“By using the term ‘consisting essentially of,’ the drafter signals that the invention necessarily includes the listed ingredients and is open to unlisted ingredients that do not materially effect the basic and novel properties of the invention.” *PPG Indus. v. Guardian Indus. Corp.*, 156 F.3d 1351, 1354, 48 U.S.P.Q.2d (BNA) 1351, 1353-54 (Fed. Cir. 1998). While those words are often used in the preamble of a claim, they may be used elsewhere in the claim to modify the scope of just one element of the claim. In the

*Mannesmann* decision, the Federal Circuit explained that such words may limit only the one element with which they appear. See *Mannesmann Demag Corp. v. Engineered Metal Prods. Co., Inc.*, 793 F.2d 1279, 230 U.S.P.Q. (BNA) 45 (Fed. Cir. 1986). Considering another scope-modifying phrase “consisting of,” the panel held, “The district court correctly observed that the phrase ‘consisting of’ appears in clause (a), not the preamble of the claim, and thus limits only the element set forth in clause (a).” *Mannesmann*, 793 F.2d at 1282, 230 U.S.P.Q. at 46.

Importantly, Appellants have substantial control over the meaning of “consisting essentially of” as used in their claims. “Under well-settled principles, [patentee] PPG was entitled to provide its own definition for the terms used in its patent claim, including the transitional phrase ‘consisting essentially of.’” *PPG Indus.*, 156 F.3d at 1355, 48 U.S.P.Q.2d at 1355. Moreover, such a phrase and definition can be added to a claim element during prosecution for the purpose of overcoming rejections based on prior art. See *Mannesmann*, 793 F.2d at 1282, 230 U.S.P.Q. at 46 (“Referring to the patent’s prosecution history, the district court observed that ‘consisting of’ was added to clause (a) by Mannesmann during prosecution in order to distinguish the claims from cited references . . .”). In the present case, Appellants also explained their use of “consisting essentially of:”

Specifically, claim 38 has been amended for the third time to recite that the composition of the claimed method comprises an active component consisting essentially of at least one 1-hydroxy-2-pyridone as defined in the claim. The “consisting essentially” language is intended to exclude those ingredients that would materially change the basic and novel characteristics of the active component in the composition employed by Applicants’ claimed method. See MPEP § 2111.03. The composition may still comprise all manner of additives, such as, for example, those described in the specification on page 7, line 36, to page 8, line 16.

Amendment filed April 24, 2002, at 18. As argued at the time by Appellants, that explanation specifically excludes the disclosure of *Saint-Leger*:

Present claim 38 now recites that the composition employed by Applicants' method comprises an active component consisting essentially of at least one 1-hydroxy-2-pyridone. By requiring a halogenated antibacterial agent, *Saint-Leger* does not describe Applicants' method of treating seborrheic dermatitis as claimed in claim 38.

*Id.* at 23; see also Appeal Brief at 20-21. Therefore, claims 38, 40-42, 48, and 65, which recite or incorporate the "consisting essentially of" language, cannot read upon the disclosure of *Saint-Leger*.

Thus, the rejections of claims 38, 40-42, and 48 based on *Saint-Leger* should be withdrawn. As explained above, *Saint-Leger* does not describe the invention set forth in those claims. Nor does *Saint-Leger* motivate the skilled artisan to reject one of *Saint-Leger's* two active ingredients to use only one. "Briefly, the present invention thus features novel dermatological/cosmetic compositions comprising at least one antifungal agent and at least one halogenated antibacterial agent, other than those of the genera macrolide and pyranoside, and to topical applications thereof for the reduction of hair loss." *Saint-Leger*, col. 2, ll. 4-9.

*Lange*, cited by the Board as extrinsic evidence to bolster this rejection (Decision at 11), does not supply the missing motivation. Instead, *Lange* enables the use of both of *Saint-Leger's* active compounds because *Lange* allows for the inclusion of "general pharmaceutics" in his "phase I" composition, and "antiseptic or disinfectant substances" in his "phase II" composition. *Lange*, col. 4, ll. 42-43, and col. 5, ll. 54-55. Moreover, *Lange* requires the use of both of the phase I and phase II compositions, foreclosing any suggestion to use just one composition. See *Lange*, col. 6, ll. 18-24; see also

Appeal Brief at 10-11. Without motivation to modify the teachings of *Saint-Leger* and *Lange* to obtain Appellants' claimed methods, those two documents cannot render Appellants' claimed methods obvious. Therefore, this rejection over *Saint-Leger* should be withdrawn, at least as to claims 38, 40-42, and 48, which recite or incorporate "consisting essentially of."

Rejection of claim 65 over *Saint-Leger* also should be withdrawn in view of the "consisting essentially of" language appearing in that claim for the same reason.

The rejection of claim 39 in view of *Saint-Leger* appearing on page 9 of the Decision should be withdrawn, given the "in need of" language explained in § I, *supra*. The alleged anticipation of claim 39 by *Saint-Leger* is further dealt with below.

III. **Claim 39 Claims a Method for Treating a Human "in Need Of" Treatment for Seborrheic Dermatitis**

Claim 39 has been rejected under 35 U.S.C. § 102 as allegedly being anticipated by *Saint-Leger*. Decision at 7. Appellants respectfully disagree with this rejection.

Claim 39 recites "[a] method of treating a human or animal patient in need of treatment for seborrheic dermatitis . . . ." However, "[t]here is no disclosure in" *Saint-Leger* that compositions described in appealed claim 39 are "administered to patients suffering from [seborrheic dermatitis] *with the intent to cure the underlying condition*." *Jansen*, 342 F.3d at 1333, 68 U.S.P.Q.2d at 1157-58; see also § I, *supra*. Accordingly, this rejection should be withdrawn.

The Decision points to controlling the growth of a certain microorganism to support this rejection. "Controlling the growth of *Pityrosporum ovale* appears to treat a symptom of seborrheic dermatitis." Decision at 8. Appellants respectfully contend,

however, that controlling the growth of *Pityrosporum ovale* does not necessarily relate to treating a symptom of seborrheic dermatitis. Those skilled in the art do not agree that *P. ovale* causes or even participates in seborrheic dermatitis. See Wortzmann Declaration, Ex. A at 3 ("Some authors claim strong evidence in favor of a pathogenic role for these microbes [*P. ovale*], whereas others do not share this view."). Instead, "[a]lthough many theories abound, the cause of seborrheic dermatitis remains unknown." *Id.* at 1.

Further, the Board cites *In re Ruscetta* for the proposition that a species anticipates a genus. See Decision at 9, n. 3 (*citing In re Ruscetta*, 255, F.2d 687, 689-90, 118 U.S.P.Q. (BNA) 101, 104 (C.C.P.A. 1958)). Appellants respectfully point out that *In re Ruscetta* is inapposite, since *Saint-Leger* does not teach a "species" of a method of treating seborrheic dermatitis. Instead, *Saint-Leger* teaches no more than treating a symptom that may be associated with seborrheic dermatitis. As discussed in § I, *supra*, treating a symptom does not rise to the level of treating a patient "in need" of treatment for the underlying disease, as claimed by Appellants.

#### IV. Conclusion

Appellants respectfully contend that this Request "states with particularity the points believed to have been misapprehended or overlooked by the Board" in its Decision. 37 C.F.R. § 41.52. Good cause has been shown for the discussion of cases not previously cited, and any arguments not previously presented respond to the new grounds of rejection advanced by the Board. See *id.* at § 41.52(a)(2) & (3).

Accordingly, Appellants ask the Board to grant this Request, and to withdraw its Decision finding the appealed claims unpatentable.

If there are any fees due that are not enclosed herewith, including any fees required for any extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 06-0916.

Respectfully submitted,  
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Dated: November 4, 2004

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